PRELIMINARY DRAFT
No. 3345

PREPARED BY
LEGISLATIVE SERVICES AGENCY
2005 GENERAL ASSEMBLY

DIGEST

Citations Affected: IC 25-26-14.

Synopsis: Wholesale drug distributor licensure. Expands the requirements that must be met by a wholesale drug distributor for eligibility for licensure in Indiana. Specifies criminal acts related to wholesale drug distribution and legend drugs.

Effective: July 1, 2005.

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 25-26-14-1 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 1. This chapter applies to any individual, partnership, limited liability company, corporation, or business firm:

(1) located within or outside Indiana; and

(2) engaging in the wholesale distribution of legend drugs ~~within~~ **in** Indiana.

SECTION 2. IC 25-26-14-1.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 1.5. As used in this chapter, "adulterated" refers to a drug that:**

(1) consists in whole or in part of a filthy, putrid, or decomposed substance;

(2) has been produced, prepared, packed, or held under unsanitary conditions and may have been contaminated or rendered injurious to health;

(3) has been subjected to conditions in the manufacture, processing, packing, or holding of the drug that do not conform to current good manufacturing practice to ensure that the drug is safe for consumption and has the identity, strength, quality, and purity characteristics that the drug is represented to possess;

(4) is contained in a container composed of a poisonous or deleterious substance that may render the contents injurious to health;

(5) bears or contains, for purposes of coloring only, a color additive that is unsafe; or

(6) is of a different strength, quality, or purity from the standard set forth for the drug in an official compendium.

SECTION 3. IC 25-26-14-1.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS

[EFFECTIVE JULY 1, 2005]: **Sec. 1.7. As used in this chapter, "authenticate" means to affirmatively verify before distribution occurs that each transaction that is listed on:**

(1) the pedigree of a drug; and

(2) other accompanying documentation;

has occurred.

SECTION 4. IC 25-26-14-1.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 1.8. As used in this chapter, "authorized distributor" means a wholesale drug distributor with which a manufacturer has established an ongoing relationship to distribute the manufacturer's products. For purposes of this section, an ongoing relationship exists between a wholesale drug distributor and a manufacturer if the wholesale drug distributor:**

(1) has a written agreement currently in effect with the manufacturer evidencing an ongoing relationship; or

(2) is listed on the manufacturer's current monthly updated list of authorized distributors.

SECTION 5. IC 25-26-14-4.1 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.1. As used in this chapter, "compendium" refers to the:**

(1) United States Pharmacopoeia;

(2) Homeopathic Pharmacopoeia of the United States;

(3) National Formulary; or

(4) a supplement to a document specified in subdivision (1), (2), or (3).

SECTION 6. IC 25-26-14-4.2 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.2. As used in this chapter, "contraband" refers to a drug:**

(1) that is counterfeit;

(2) that is stolen;

(3) that is misbranded;

(4) that is obtained by fraud;

(5) that is purchased by a nonprofit institution for the nonprofit institution's own use and placed in commerce in violation of the own use agreement for the drug;

(6) for which a required pedigree does not exist; or

(7) for which a pedigree in existence has been forged, counterfeited, or falsely created, or contains any altered, false, or misrepresented information.

SECTION 7. IC 25-26-14-4.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.3. As used in this chapter, "counterfeit" refers to a drug, or the container, seal, or labeling of**

a drug, that, without authorization, bears the trademark, trade name, or other identifying mark, imprint of a manufacturer, processor, packer, or distributor other than the person that manufactured, processed, packed, or distributed the drug.

SECTION 8. IC 25-26-14-4.4 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.4. As used in this chapter, "deliver" means the actual, constructive, or attempted transfer of a drug from one (1) person to another.**

SECTION 9. IC 25-26-14-4.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.5. As used in this chapter, "designated representative" means an individual who is designated by a wholesale drug distributor and who:**

(1) serves as the responsible individual of the wholesale drug distributor with the board; and

(2) is actively involved in and aware of the actual daily operation of the wholesale drug distributor.

SECTION 10. IC 25-26-14-4.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.6. As used in this chapter, "device" means an instrument, an apparatus, an implement, a machine, a contrivance, an implant, or a similar or related article, including a component part or accessory, that is required under federal law to bear the label "Caution: Federal or State law requires dispensing by or on the order of a physician.".**

SECTION 11. IC 25-26-14-4.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.7. As used in this chapter, "distribute" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a legend drug, whether by passage of title, physical movement, or both. The term does not include the following:**

(1) Dispensing or administering a legend drug.

(2) Delivering or offering to deliver a legend drug by a common carrier in the usual course of business as a common carrier.

(3) The provision of a drug sample to a patient by a:

(A) practitioner;

(B) health care professional acting at the direction and under the supervision of a practitioner; or

(C) hospital's or other health care entity's pharmacy that received the drug sample in accordance with this chapter and other applicable law to administer or dispense and acting at the direction of a practitioner;

licensed to prescribe the legend drug.

SECTION 12. IC 25-26-14-4.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.8. As used in this chapter, "drug" means the following:**

(1) Articles recognized in an official compendium and designated by the board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals.

(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals.

(3) Articles other than food intended to affect the structure or function of the body of humans or animals.

(4) Articles intended for use as a component of an article specified in subdivision (1), (2), or (3).

The term does not include devices or device components, parts, or accessories.

SECTION 13. IC 25-26-14-6 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 6. As used in this chapter, "health care entity" means any organization or business that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care. **The term does not include a pharmacy or wholesale drug distributor.**

SECTION 14. IC 25-26-14-6.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 6.5. As used in this chapter, "label" means a display of written, printed, or graphic matter on the immediate container of a legend drug.**

SECTION 15. IC 25-26-14-6.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 6.6. As used in this chapter, "labeling" means labels and other written, printed, or graphic matter:**

(1) on a legend drug or a legend drug's container or wrapper; or

(2) accompanying a legend drug.

SECTION 16. IC 25-26-14-8.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 8.3. As used in this chapter, "misbranded" means that a legend drug's label:**

(1) is false or misleading;

(2) does not bear the name and address of the manufacturer, packer, or distributor or does not contain an accurate statement of the quantities of active ingredients of the legend drug;

(3) does not show an accurate monograph for the legend drug; or

(4) does not comply with any other requirements of the federal Food, Drug and Cosmetic Act.

SECTION 17. IC 25-26-14-8.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 8.7. As used in this chapter, "pedigree" means a document in a written or an electronic form that is approved by the board, that records each distribution of a legend drug, from the sale by a manufacturer through acquisition and sale by a wholesale drug distributor, and that includes the following information for each transaction:**

(1) The source of the legend drug, including the name and principal address of the seller.

(2) The:

(A) amount and dosage form and strength;

(B) date of purchase;

(C) sales invoice number;

(D) container size;

(E) number of containers; and

(F) lot number;

of the legend drug.

(3) The:

(A) business name and address of each owner of the legend drug; and

(B) legend drug's shipping information, including the name and address of the facility of each person certifying delivery or receipt of the legend drug.

(4) Information that states that the wholesale drug distributor has conducted due diligence, if required under this chapter, of another wholesale drug distributor from which the wholesale drug distributor purchased or may have purchased the legend drug.

(5) A certification from the designated representative of the wholesale drug distributor that the information contained in the document is true and accurate under penalty of perjury.

SECTION 18. IC 25-26-14-9 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 9. As used in this chapter, "person" means an individual, a partnership, a business firm, a limited liability company, ~~or~~ a corporation, **or another entity, including a governmental entity.**

SECTION 19. IC 25-26-14-9.2 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 9.2. As used in this chapter, "practitioner" has the meaning set forth in IC 16-42-19-5.**

SECTION 20. IC 25-26-14-9.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 9.3. As used in this chapter,**

"repackage" means changing the container, wrapper, quantity, or labeling of a legend drug to further the distribution of the legend drug.

SECTION 21. IC 25-26-14-10.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 10.5. As used in this chapter, "specified list of susceptible products" means a specific list of legend drugs designated by the board, or a third party approved by the board, as:**

(1) being susceptible to adulteration, counterfeiting, or diversion; and

(2) posing the potential for a particular public health risk.

SECTION 22. IC 25-26-14-14 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 14. (a) ~~After September 14, 1992,~~ A person may not engage in wholesale distributions of legend drugs without having a license from the board and paying any reasonable fee required by the board.

(b) The board may not issue or renew the license of a wholesale drug distributor that does not comply with this chapter.

(c) The board ~~may~~ **shall** require a separate license for

~~(1)~~ each facility ~~directly or indirectly owned or operated by the same business in Indiana; or~~

~~(2) a parent entity with divisions, subsidiaries, or affiliate companies in Indiana when operations are conducted at more than one (1) location and there exists joint ownership and control among all the entities.~~ **or location where wholesale distribution operations are conducted.**

(d) An agent or employee of any licensed wholesale drug distributor does not need a license and may lawfully possess pharmaceutical drugs when acting in the usual course of business or employment.

(e) The issuance of a license under this chapter does not affect tax liability imposed by the department of state revenue or the department of local government finance on any wholesale drug distributor.

(f) The board may adopt rules that permit out-of-state wholesale drug distributors to obtain a license on the basis of reciprocity if:

(1) an out-of-state wholesale drug distributor possesses a valid license granted by another state and the legal standards for licensure in the other state are comparable to the standards under this chapter; and

(2) the other state extends reciprocity to wholesale drug distributors licensed in Indiana.

However, if the requirements for licensure under this chapter are more stringent than the standards of the other state, the out-of-state wholesale drug distributor must comply with the additional requirements of this chapter to obtain a license under this chapter.

SECTION 23. IC 25-26-14-15 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 15. (a) The board shall require the following minimum information from each wholesale drug distributor as part of the license described in section 14 of this chapter and as part of any renewal of such license:

(1) The name, full business address, and telephone number of the licensee.

(2) All trade or business names used by the licensee.

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of legend drugs.

(4) The type of ownership of operation.

(5) The name of each owner and operator of the licensee, including:

(A) if an individual, the name, **address, Social Security number, and date of birth** of the individual;

(B) if a partnership, the name, **address, Social Security number, and date of birth** of each partner, and the name of the partnership **and federal employer identification number;**

(C) if a corporation:

(i) the name, **address, Social Security number, date of birth,** and title of each corporate officer and director;

(ii) the corporate names, ~~and~~ the name of the state of incorporation, **the federal employer identification number, and the name of the parent company, if any;**

(iii) the name, address, and Social Security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, unless the stock is traded on a major stock exchange and not traded over the counter;

(D) if a limited liability company, the name of each manager and member, the name **and federal identification number** of the limited liability company, and the name of the state where organized; and

(E) if a sole proprietorship, the full name, **address, Social Security number, and date of birth** of the sole proprietor and the name **and federal employer identification number** of the business entity.

(6) The name, **address, and telephone number** of the person designated by the licensee as responsible for the operation of ~~the facilities.~~ **each facility of the licensee that engages in the distribution of legend drugs and additional information concerning record keeping as required under this chapter.**

(b) The board shall require a wholesale drug distributor to post a surety bond of at least one hundred thousand dollars ($100,000), or an equivalent means of security acceptable to the board, to

secure payment of any administrative penalties that may be imposed by the board and any fees and costs that may be incurred by the board and that:

(1) are related to a license held by the wholesale drug distributor;

(2) are authorized under state law; and

(3) the wholesale drug distributor fails to pay less than thirty (30) days after the penalties, fees, or costs become final.

(c) The board may make a claim against a bond or security posted under subsection (b) within one (1) year after the conclusion of:

(1) an administrative or legal proceeding before or on behalf of the board that involves the wholesale drug distributor and results in penalties, fees, or costs described in subsection (b); or

(2) an appeal of a proceeding described in subdivision (1);

whichever occurs later.

(d) A manufacturer must establish and update on a monthly basis a list of authorized distributors approved by the manufacturer. The list under this subsection must be made available upon request or on the Internet.

(e) A manufacturer shall file a written list of all of the manufacturer's authorized distributors with the board. A manufacturer shall notify the board not more than ten (10) days after any change to the list. The board shall make the list available on the board's Internet site.

(f) The board shall inspect each facility where wholesale distribution operations are conducted before initial licensure and periodically thereafter in accordance with a schedule determined by the board, but at least one (1) time in each three (3) year period.

(g) A wholesale drug distributor must publicly display or have readily available all licenses and the most recent inspection report administered by the board.

~~(b)~~ **(h)** A material change in any information in ~~subsection (a) of~~ this section must be submitted to the board at the time of license renewal or within thirty (30) days from the date of the change, whichever occurs first.

SECTION 24. IC 25-26-14-16 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 16. **(a)** In reviewing, **for purposes of licensure or renewal of a license under this chapter,** the qualifications of persons who engage in wholesale distribution of legend drugs ~~within~~ **in** Indiana, the board shall consider the following factors:

(1) A ~~conviction of the applicant relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances.~~ **finding by the board that the applicant has:**

(A) violated a law; or

(B) been disciplined by a regulatory agency for violating a law;

in any state related to drug distribution.

(2) A ~~felony~~ **criminal** conviction of the applicant.

(3) The applicant's past experience in the manufacture or distribution of legend drugs, including controlled substances.

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution.

(5) Suspension or revocation **of any license held by the applicant or the applicant's owner or the imposition of sanctions against the applicant or the applicant's owner** by the federal, ~~or~~ a state, **or a local** government ~~of any license held by the applicant~~ for the manufacture or distribution of any drugs, including controlled substances.

(6) Compliance with licensing requirements under previously granted licenses.

(7) Compliance with requirements to maintain and make available to the board or to federal, state, or local law enforcement officials those records required under this chapter.

(8) Any other factors or qualifications the board considers relevant to the public health and safety, including whether the granting of the license would not be in the public interest.

(b) In reviewing an application for licensure or renewal of a license under this chapter, the board shall consider the results of a criminal history background check of:

(1) the applicant;

(2) all personnel involved in the operations of the wholesale drug distributor;

(3) the most senior individual responsible for facility operations, purchasing, and inventory control, and the individual to whom the senior individual reports;

(4) company officers;

(5) key management personnel;

(6) principals; and

(7) owners with a ten percent (10%) or greater interest in the wholesale drug distributor, if the wholesale drug distributor is a nonpublicly held company.

The criminal history background check must be conducted in compliance with state law, at the applicant's expense, and must include all states of residence since the individual became eighteen (18) years of age.

(c) An applicant shall provide and attest to:

(1) an affirmation that the applicant has not been involved in or convicted of any criminal or prohibited acts; or

(2) a statement providing a complete disclosure of the applicant's past criminal convictions and violations of state and federal laws regarding drugs.

SECTION 25. IC 25-26-14-16.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 16.5. (a) A wholesale drug distributor licensed under this chapter shall designate in writing on a form prescribed by the board a designated representative for each facility licensed under this chapter.**

(b) A designated representative shall submit to the board an application prescribed by the board and provide to the board the following:

(1) A set of the designated representative's fingerprints, under procedures specified by the board, with the payment of the amount equal to the costs incurred by the board for a criminal history background check of the designated representative.

(2) The date and place of birth of the designated representative.

(3) A list of the occupations, positions of employment, and offices held by the designated representative during the immediately preceding seven (7) years, including the principal business and address of the organization with which the occupation, position, or office was associated.

(4) A statement concerning whether the designated representative, during the immediately preceding seven (7) years, has been temporarily or permanently enjoined by a court from violating a state or federal law regulating the possession, control, or distribution of drugs, including details of related events.

(5) A description of any involvement by the designated representative with any business that:

(A) manufactured, administered, prescribed, distributed, or stored drugs; and

(B) was named as a party in a lawsuit;

during the immediately preceding seven (7) years, including investments other than the ownership of stock in a publicly traded company or mutual fund.

(6) A description of any criminal offense, other than a minor traffic offense, of which the designated representative has been found guilty as an adult, regardless of whether adjudication of guilt was withheld or whether the designated representative pled guilty or nolo contendere. If the designated representative indicates that a criminal conviction is under appeal, the designated representative shall submit to the board a copy of the notice of appeal and, not more than

fifteen (15) days after the disposition of the appeal, a copy of the final written order of disposition.

(7) A photograph of the designated representative taken within the immediately preceding thirty (30) days under procedures specified by the board.

(8) A list of the name, address, occupation, date, and place of birth of each member of the designated representative's immediate family, including the designated representative's spouse, children, parents, and siblings, and the spouses of the designated representative's children and siblings.

(9) Any other information required by the board.

(c) A designated representative must have at least two (2) years of verifiable full-time managerial or supervisory experience in a pharmacy or with a wholesale drug distributor licensed under this chapter or in another state. The designated representative's responsibilities must have included record keeping, storage, and shipment of legend drugs.

(d) A designated representative shall not serve as the designated representative for more than one (1) wholesale drug distributor at any one (1) time.

(e) A designated representative shall be actively involved and aware of the actual daily operations of the wholesale drug distributor, as follows:

(1) Be employed full time in a managerial position by the wholesale drug distributor.

(2) Be physically present at the wholesale drug distributor's facility during normal business hours, except when absent due to illness, family illness or death, scheduled vacation, or another authorized absence.

(3) Be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale drug distributor.

(f) A designated representative must complete continuing education programs specified by the board regarding state and federal law relevant to the distribution, handling, and storage of legend drugs.

(g) A licensed wholesale drug distributor located outside Indiana that distributes legend drugs in Indiana shall designate a registered agent in Indiana for service of process. A licensed wholesale drug distributor that does not designate a registered agent is considered to have designated the secretary of state of Indiana to be the wholesale drug distributor's true and lawful attorney, upon whom legal process may be served in an action or a proceeding against the wholesale drug distributor arising from the wholesale drug distributor's wholesale distribution operations. The board shall mail a copy of any service of process to the

wholesale drug distributor by certified mail, return receipt requested, postage prepaid, at the address designated by the wholesale drug distributor on the application for licensure submitted under this chapter. If a wholesale drug distributor is not licensed under this chapter, service on the secretary of state is sufficient.

SECTION 26. IC 25-26-14-17 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 17. As a condition for receiving and retaining ~~any~~ **a** wholesale drug distributor license issued under ~~to~~ this chapter, ~~each~~ **an** applicant must satisfy the board that the applicant has and will continuously maintain the following:

(1) Acceptable storage and handling conditions and facilities standards **for all facilities at which legend drugs are received, stored, warehoused, handled, held, offered, marketed, or displayed, or from which legend drugs are transported, including:**

(A) suitable construction of facilities and appropriate monitoring equipment to ensure that legend drugs in the facilities are maintained in accordance with labeling or in compliance with official compendium standards;

(B) suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations;

(C) adequate storage areas to provide appropriate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(D) a quarantine area for separate storage of legend drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, suspected counterfeit, otherwise unfit for distribution, or contained in immediate or sealed secondary containers that have been opened;

(E) maintenance of the facilities in a clean and orderly condition;

(F) maintenance of all facilities in commercial, nonresidential buildings; and

(G) freedom of facilities from infestation.

(2) **Facilities secure from unauthorized entry as follows:**

(A) Entry into areas where legend drugs are held are limited to authorized personnel.

(B) Each facility is equipped with a security system that includes:

~~(A)~~ **(i)** an after hours central alarm or a comparable entry detection capability;

~~(B)~~ **(ii)** restricted premises access;

~~(C)~~ **(iii)** adequate outside perimeter lighting; ~~and~~

~~(D)~~ **(iv)** safeguards against **theft and diversion, including**

employee theft **and theft or diversion facilitated or hidden by tampering with computers or electronic records; and**

(v) a means of protecting the integrity and confidentiality of data and documents and of making the data and documents readily available to the board and other state and federal law enforcement officials.

(3) A reasonable system of record keeping ~~that~~ **as follows:**

(A) **The system** describes all the wholesale distributor's activities governed by this chapter for the ~~two (2)~~ **three (3)** year period after the disposition of each product and **all records are maintained for at least three (3) years after disposition of the legend drug to which the record applies.**

(B) **The system** is reasonably accessible as determined by board rules in any inspection authorized by the board.

(C) The system provides a means to establish and maintain inventories and records of transactions regarding the receipt and distribution or other disposition of all legend drugs, including the following:

(i) If the wholesale drug distributor is an authorized distributor for a legend drug, a pedigree for each distributed legend drug that is on the specified list of susceptible products.

(ii) If the wholesale drug distributor is not an authorized distributor for a legend drug, a pedigree for each distributed legend drug.

(iii) Effective January 1, 2007, an electronic pedigree developed in accordance with standards and requirements of the board for each legend drug received and distributed by the wholesale drug distributor.

(iv) Dates of receipt and distribution or other disposition of the legend drugs by the wholesale drug distributor.

(v) Availability for inspection and photocopying by any authorized official of a local, state, or federal governmental agency for three (3) years after the creation date of the inventories and records.

(D) Onsite electronic inventories and records are immediately available for inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable are available for inspection within two (2) working days of a request by an authorized official of a local, state, or federal governmental agency.

(E) The system maintains an ongoing list of persons with whom the wholesale drug distributor does business.

(F) The system provides for reporting counterfeit or suspected counterfeit legend drugs or counterfeiting or

suspected counterfeiting activities to the board and federal Food and Drug Administration.

(G) The system provides for mandatory reporting of significant shortages or losses of legend drugs to the board and federal Food and Drug Administration if diversion is known or suspected.

(4) Written policies and procedures **to which the wholesale drug distributor adheres for the receipt, security, storage, inventory, transport, shipping, and distribution of legend drugs, and** that assure reasonable wholesale distributor preparation for, protection against, and handling of any facility security or operation problems, including **the following:**

(A) ~~those~~ **Facility security or operation problems** caused by natural disaster or government emergency.

(B) **Correction of** inventory inaccuracies. ~~or~~

(C) Product shipping and receiving **problems.**

~~(C)~~ **(D) Quarantine, return to the manufacturer, or destruction in accordance with state and federal law of all** outdated product **and outdated or expired legend drugs, including appropriate documentation and witnessing.**

~~(D)~~ **(E)** Appropriate disposition of returned goods. ~~and~~

~~(E)~~ **(F)** Product recalls.

(G) Identifying, recording, and reporting losses or thefts.

(H) Implementation and maintenance of a continuous quality improvement system.

(I) Recalls and withdrawals of legend drugs due to:

(i) an action initiated by the federal Food and Drug Administration or another federal, state, or local agency;

(ii) a volunteer action by the manufacturer to remove defective or potentially defective legend drugs from the market; or

(iii) an action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design.

(J) Disposition and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging are not used in counterfeiting activities, including necessary documentation and witnessing in accordance with state and federal law.

(K) Investigation of discrepancies in the inventory involving counterfeit, suspected counterfeit, contraband, or suspected contraband legend drugs and reporting of discrepancies within three (3) business days to the board and any other appropriate state or federal agency.

(L) Reporting of criminal or suspected criminal activities involving the inventory of legend drugs to the board within

three (3) business days.

(M) Conducting for cause pedigree authentication and random pedigree authentication as required under section 17.9 of this chapter.

(5) Sufficient inspection procedures for all incoming and outgoing product shipments, **including the following:**

(A) Upon receipt, each shipping container is visually examined in a manner adequate to identify the legend drugs in the container and to determine whether the legend drugs may be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, suspected counterfeit, damaged, or otherwise unfit for distribution.

(B) Legend drugs found to be unacceptable under clause (A) are quarantined until examination and a determination that the legend drugs are not outdated, adulterated, misbranded, contaminated, contraband, counterfeit, or damaged, and that they are fit for human use.

(C) Each outgoing shipment is carefully inspected for identity of the legend drugs and to ensure that the legend drugs have not been damaged in storage or held under improper conditions.

(D) Upon receipt, the wholesale drug distributor reviews records for the acquisition of legend drugs for accuracy and completeness, considering the:

(i) total facts and circumstances surrounding each transaction involving the legend drugs; and

(ii) wholesale drug distributors involved.

(6) Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.

(7) Written policies and procedures to provide for the secure and confidential storage of information with restricted access and to protect the integrity and confidentiality of the information.

(8) A pedigree from the wholesale distribution of legend drugs before the transaction to another wholesale drug distributor in accordance with the record keeping requirements of this chapter.

(9) Appropriate inventory management and control systems to:

(A) prevent; and

(B) allow detection and documentation of;

theft, counterfeiting, or diversion of legend drugs.

(10) If the wholesale drug distributor is involved in the distribution of controlled substances, registration with the federal Drug Enforcement Administration and board and compliance with all laws related to the storage, handling,

transport, shipment, and distribution of controlled substances.

(11) Technology and equipment that allows the wholesale drug distributor to authenticate, track, and trace legend drugs. The technology and equipment meets standards set by the board and is used as required by the board to conduct for cause and random tracking, tracing, and authentication of legend drugs. Employment, training, and documentation of the training concerning the proper use of the technology and equipment.

(12) Packaging operations in accordance with an official compendium allowing the identification of a compromise in the integrity of the legend drugs due to tampering or adverse storage conditions.

(13) Isolation of controlled substances from noncontrolled substances and storage of the controlled substances in a secure area in accordance with federal Drug Enforcement Administration security requirements and standards.

(14) Written policies and procedures to ensure the following:

(A) That a legend drug that was:

(i) ordered in error or in excess of need by the wholesale drug distributor;

(ii) identified within three (3) business days as ordered in error or in excess of need; and

(iii) maintained such that the legend drug's integrity has not been compromised;

may be returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired if the appropriate documentation is completed and necessary notations are made to the required pedigree.

(B) That a legend drug that is outdated, damaged, deteriorated, misbranded, counterfeit, suspected counterfeit, adulterated, or otherwise unfit for human consumption is quarantined until the legend drug is returned to either the manufacturer or wholesale drug distributor from which the legend drug was acquired.

(C) That if a wholesale drug distributor determines that a legend drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the legend drug was acquired within three (3) business days.

(D) That:

(i) a legend drug returned to a manufacturer or wholesale drug distributor is kept under proper conditions for storage, handling, transport, and shipment; and

(ii) documentation showing that proper conditions were maintained is provided to the manufacturer or wholesale drug distributor to which the legend drug is returned.

(E) That if the immediate or sealed outer or secondary container or labeling of a legend drug are adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor:

(i) quarantines the legend drug until the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired; and

(ii) provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the drug was acquired within three (3) business days.

(F) That a legend drug that has been opened or used, but is not adulterated, misbranded, counterfeit, or suspected counterfeit, is identified as such, and quarantined until the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired.

(G) That if conditions under which a legend drug has been returned cast doubt on the legend drug's safety, identity, strength, quality, or purity, the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired unless examination, testing, or other investigation proves that the legend drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a legend drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor considers the conditions under which the legend drug has been held, stored, or shipped before or during the legend drug's return and the condition of the legend drug and the legend drug's container, carton, or labeling, as a result of holding, storage, or shipping.

(H) That contraband, counterfeit, or suspected counterfeit legend drugs, other evidence of criminal activity, and accompanying documentation are retained until a disposition is authorized by the board and the federal Food

and Drug Administration.

(I) That any shipping, immediate, or sealed outer or secondary container or labeling, and accompanying documentation, suspected of or determined to be counterfeit or fraudulent are retained until a disposition is authorized by the board and federal Food and Drug Administration.

SECTION 27. IC 25-26-14-17.2 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 17.2. (a) A wholesale drug distributor that purchases legend drugs from another wholesale drug distributor and has reason to believe that a legend drug purchased from the other wholesale drug distributor is counterfeit, suspected counterfeit, misbranded, or adulterated shall authenticate each distribution of the legend drug back to the manufacturer.**

(b) A wholesale drug distributor that has engaged in the distribution of a legend drug for which a purchasing wholesale drug distributor conducts a for cause authentication shall provide, upon request, detailed information regarding the distribution of the legend drug, including the:

(1) date of purchase of the legend drug;

(2) lot number of the legend drug;

(3) sales invoice number of the legend drug; and

(4) contact information, including name, address, telephone number, and e-mail address, of the wholesale drug distributor that sold the legend drug.

(c) If a wholesale drug distributor attempts to authenticate the distribution of a legend drug back to the manufacturer and is unable to authenticate each distribution of the legend drug, the wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration not more than ten (10) business days after completing the attempted authentication.

(d) If a wholesale drug distributor authenticates the distribution of a legend drug back to the manufacturer, the wholesale drug distributor shall maintain records of the authentication for three (3) years and shall produce the records for the board and the federal Food and Drug Administration upon request.

SECTION 28. IC 25-26-14-17.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 17.3. (a) A wholesale drug distributor that purchases legend drugs from another wholesale drug distributor shall, at least annually, conduct a random authentication of the required pedigree on at least ten percent (10%) of sales units of wholesale distributions of legend drugs**

purchased from other wholesale drug distributors.

(b) If a wholesale drug distributor has purchased from another wholesale drug distributor a legend drug that is on the specified list of susceptible products, the wholesale drug distributor shall, at least quarterly, conduct a random authentication of the required pedigree on at least ninety percent (90%) of sales units of distributions of legend drugs that are on the specified list of susceptible products that were purchased from other wholesale drug distributors.

(c) A wholesale drug distributor from whom another wholesale drug distributor purchases legend drugs shall cooperate with random authentications of pedigrees described in this section and provide requested information in a timely manner.

SECTION 29. IC 25-26-14-17.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 17.8. A wholesale drug distributor licensed under this chapter may not use a trade name or business name identical to a trade name or business name used by another wholesale drug distributor licensed under this chapter.**

SECTION 30. IC 25-26-14-17.9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 17.9. (a) A wholesale drug distributor licensed under this chapter that purchases legend drugs from a wholesale drug distributor that is not licensed under this chapter shall perform due diligence under this section.**

(b) Before the initial purchase of legend drugs from the unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall obtain the following information from the unlicensed wholesale drug distributor:

(1) A list of states in which the unlicensed wholesale drug distributor is licensed.

(2) A list of states into which the unlicensed wholesale drug distributor ships legend drugs.

(3) Copies of all state and federal regulatory licenses and registrations held by the unlicensed wholesale drug distributor.

(4) The unlicensed wholesale drug distributor's most recent facility inspection reports.

(5) Information regarding general and product liability insurance maintained by the unlicensed wholesale drug distributor, including copies of relevant policies.

(6) A list of other names under which the unlicensed wholesale drug distributor does business or has been previously known.

(7) A list of corporate officers and managerial employees of the unlicensed wholesale drug distributor.

(8) A list of all owners of the unlicensed wholesale drug

distributor that own more than ten percent (10%) of the unlicensed wholesale drug distributor, unless the unlicensed wholesale drug distributor is publicly traded.

(9) A list of all disciplinary actions taken against the unlicensed wholesale drug distributor by state and federal agencies.

(10) A description, including the address, dimensions, and other relevant information, of each facility used by the unlicensed wholesale drug distributor for legend drug storage and distribution.

(11) A description of legend drug import and export activities of the unlicensed wholesale drug distributor.

(12) A description of the unlicensed wholesale drug distributor's procedures to ensure compliance with this chapter.

(13) A statement:

(A) as to whether; and

(B) of the identity of each manufacturer for which;

the unlicensed wholesale drug distributor is an authorized distributor of record.

(c) Before the initial purchase of legend drugs from an unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall:

(1) conduct a criminal history background check of all individuals associated with the unlicensed wholesale drug distributor as specified for licensure of a wholesale drug distributor under section 16(b) of this chapter; and

(2) verify the unlicensed wholesale drug distributor's status as an authorized distributor of record, if applicable.

(d) If an unlicensed wholesale drug distributor's facility has not been inspected by the board or the board's agent within three (3) years of a contemplated purchase described in subsection (a), the licensed wholesale drug distributor shall conduct an inspection of the unlicensed wholesale drug distributor's facility:

(1) before the initial purchase of legend drugs from the unlicensed wholesale drug distributor; and

(2) at least once every three (3) years unless the unlicensed wholesale drug distributor's facility has been inspected by the board, or the board's agent, during the same period;

to ensure compliance with applicable laws and regulations relating to the storage and handling of legend drugs. A third party may be engaged to conduct the site inspection on behalf of the licensed wholesale drug distributor.

(e) At least annually, a licensed wholesale drug distributor that purchases drugs from an unlicensed wholesale drug distributor shall update the information specified in section 17(3) of this

chapter.

(f) If a licensed wholesale drug distributor that purchases drugs from an unlicensed wholesale drug distributor has reason to believe, based on the totality of the facts and circumstances, that a legend drug purchased from the unlicensed wholesale drug distributor is counterfeit, suspected counterfeit, misbranded, or adulterated, the licensed wholesale drug distributor must authenticate each distribution of the legend drug back to the manufacturer.

(g) An unlicensed wholesale drug distributor that has engaged in the distribution of a legend drug for which a licensed wholesale drug distributor conducts a for cause authentication shall provide, upon request, detailed information regarding the distribution of the legend drug, including the:

(1) date of purchase of the legend drug;

(2) lot number the legend drug;

(3) sales invoice number of the legend drug; and

(4) contact information, including name, address, telephone number, and any e-mail address, of the unlicensed wholesale drug distributor that sold the legend drug.

(h) If a licensed wholesale drug distributor attempting to authenticate the distribution of a legend drug back to a manufacturer under subsection (f) is unable to authenticate each distribution of the legend drug, the licensed wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and federal Food and Drug Administration within three (3) business days after completing the attempted authentication.

(i) If a licensed wholesale drug distributor authenticates the distribution of a legend drug back to the manufacturer under subsection (f), the licensed wholesale drug distributor shall maintain records of the authentication for three (3) years and shall provide the records to the board upon request.

(j) A licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor shall, at least annually, conduct random authentications of required pedigrees on at least ten percent (10%) of sales units of distributions of legend drugs that were purchased from unlicensed wholesale drug distributors.

(k) A licensed wholesale drug distributor that has purchased a legend drug that is on the specified list of susceptible products shall, at least quarterly, conduct random authentications of required pedigrees on at least ninety percent (90%) of sales units of distributions of legend drugs that:

(1) are on the specified list of susceptible products; and

(2) were purchased from unlicensed wholesale drug

distributors.

(l) An unlicensed wholesale drug distributor from which a licensed wholesale drug distributor has purchased drugs shall cooperate with the random authentications of pedigrees under this section and provide requested information in a timely manner.

SECTION 31. IC 25-26-14-20 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 20. **(a)** A person employed in wholesale distribution must have appropriate education or experience to assume responsibility for positions related to compliance with licensing requirements.

(b) Before employing a person to be engaged in the operation and handling of legend drugs, a wholesale drug distributor shall obtain a criminal history background check for the person.

SECTION 32. IC 25-26-14-21 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 21. (a) A wholesale drug distributor license expires at midnight of the **annual** renewal date specified by the health professions bureau under IC 25-1-5-4. ~~in each even-numbered year.~~

(b) The board shall mail renewal application forms to each licensed wholesale drug distributor before the first day of the month before the month in which the license expires. If an application for renewal has not been filed and the required fee paid before the license expiration date, the wholesale drug distributor license shall lapse and become void.

(c) A lapsed license may be reinstated only by meeting the requirements under IC 25-1-8-6.

(d) A wholesale drug distributor may not be open for business after the license has lapsed until the renewal is completed.

SECTION 33. IC 25-26-14-21.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 21.5. A person may not perform, cause the performance of, or aid or abet the performance of the following:**

(1) The manufacture, repackaging, sale, delivery, holding, or offering for sale of a legend drug that is adulterated, misbranded, counterfeit, suspected counterfeit, or has otherwise been rendered unfit for distribution.

(2) The adulteration, misbranding, or counterfeiting of a legend drug.

(3) The receipt of a legend drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected counterfeit, and the delivery or proffered delivery of the legend drug for pay or otherwise.

(4) The alteration, mutilation, destruction, obliteration, or removal of the whole or a part of the labeling of a legend drug or the commission of another act with respect to a legend drug

that results in the legend drug being misbranded.

(5) Forging, counterfeiting, simulating, or falsely representing a legend drug using a mark, stamp, tag, label, or other identification device without the authorization of the manufacturer.

(6) The purchase or receipt of a legend drug from a person that is not licensed to distribute legend drugs to the purchaser or recipient.

(7) The sale or transfer of a legend drug to a person that is not authorized under the law of the jurisdiction in which the person receives the legend drug to purchase or receive legend drugs from the person selling or transferring the legend drug.

(8) Failure to maintain or provide records as required under this chapter.

(9) Providing the board or a representative of the board or a state or federal official with false or fraudulent records or making false or fraudulent statements regarding a matter related to this chapter.

(10) The wholesale distribution of a legend drug that was:

(A) purchased by a public or private hospital or other health care entity;

(B) donated or supplied at a reduced price to a charitable organization; or

(C) stolen or obtained by fraud or deceit.

(11) Obtaining or attempting to obtain a legend drug by fraud, deceit, misrepresentation, or engaging in misrepresentation or fraud in the distribution of a legend drug.

(12) Failure to obtain, authenticate, or pass on a required pedigree.

(13) The receipt of a legend drug through wholesale distribution without first receiving a required pedigree attested to as accurate and complete by the wholesale drug distributor.

(14) Distributing a legend drug that was previously dispensed by a retail pharmacy or distributed by a practitioner.

(15) Failure to report an act prohibited by this subsection.

SECTION 34. IC 25-26-14-26 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 26. **(a)** A person that engages in the wholesale distribution of a legend drug without a license issued under this chapter commits a Class D felony.

(b) A person that engages in the wholesale distribution of a legend drug and:

(1) that, with intent to defraud or deceive:

(A) fails to deliver to another person a complete and accurate required pedigree concerning a legend drug

before:

(i) transferring the legend drug to another person; or

(ii) obtaining the legend drug from another person; or

(B) falsely swears or certifies that the person has authenticated any documents related to the wholesale distribution of legend drugs;

(2) that knowingly:

(A) destroys, alters, conceals, or fails to maintain a complete and accurate pedigree concerning a legend drug in the person's possession;

(B) purchases or receives legend drugs from a person not authorized to distribute legend drugs in wholesale distribution;

(C) sells, barters, brokers, or transfers a legend drug to a person not authorized to purchase the legend drug in the jurisdiction in which the person receives the legend drug in a wholesale distribution;

(D) forges, counterfeits, or falsely creates a pedigree;

(E) falsely represents a factual matter contained in a pedigree; or

(F) fails to record material information required to be recorded in a pedigree; or

(3) that:

(A) is in possession of a required pedigree concerning a legend drug;

(B) knowingly fails to authenticate the matters contained in the pedigree as required; and

(C) distributes or attempts to further distribute the legend drug;

commits a Class D felony.

[NOTE: WILL POSSIBLY MOVE (c), (d), and repeat of (e) TO TITLE 35]

(c) A person that knowingly:

(1) possesses, actually or constructively, an amount of a contraband legend drug; or

(2) sells, delivers, or possesses with intent to sell or deliver an amount of a contraband legend drug;

(3) forges, counterfeits, or falsely creates a label for a legend drug or who falsely represents a factual matter contained in a label of a legend drug; or

(4) manufactures, purchases, sells, delivers, or brings into Indiana, or that is knowingly in actual or constructive possession of an amount of a contraband legend drug;

commits a Class D felony.

(d) A person that knowingly manufactures, purchases, sells, delivers, or brings into Indiana, or that is knowingly in actual or

constructive possession of an amount of a contraband legend drug, and whose acts result in the death of an individual commits a Class A felony.

(e) If a person is found guilty of an offense specified in subsections (b) through (d), the court convicting and sentencing the person may order that the person forfeit to the state the following real or personal property:

(1) Property used or intended to be used to commit, facilitate, or promote the commission of the offense.

(2) Property constituting, derived from, or traceable to the gross proceeds that the person obtained directly or indirectly as a result of the offense.

Property or assets subject to forfeiture under this subsection may be seized under a warrant obtained in the same manner as a search warrant or as otherwise permitted by law and may be held until the case against the person is adjudicated.

SECTION 35. IC 25-26-14-27 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 27. A wholesale drug distributor that fails to comply with the conditions **and requirements** described in section 17, **17.2, 17.3, 17.8, 17.9, or 20** of this chapter commits a Class D felony.